

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 10/023,254 12/17/2001 Alexander Goen Szynalski NutriMerica 4735 22925 7590 04/13/2004 EXAMINER PHARMACEUTICAL PATENT ATTORNEYS, POHL & ASSOC. FERNSTROM, KURT 55 MADISON AVENUE, 4TH FLOOR ATTN: MARK POHL (P 4014) ART UNIT PAPER NUMBER MORRISTOWN, NJ 07960-6397 3712

DATE MAILED: 04/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)	
	10/023,254	SZYNALSKI,	ALEXANDER GOEN
Office Action Summary	Examiner	Art Unit	
	Kurt Fernstrom	3712	
The MAILING DATE of this communication Period for Reply	appears on the cover she	et with the correspondence	address
A SHORTENED STATUTORY PERIOD FOR RE THE MAILING DATE OF THIS COMMUNICATIO - Extensions of time may be available under the provisions of 37 CFF after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a - If NO period for reply is specified above, the maximum statutory per - Failure to reply within the set or extended period for reply will, by sta Any reply received by the Office later than three months after the mearned patent term adjustment. See 37 CFR 1.704(b).	N. R. 1.136(a). In no event, however, melow within the statutory minimum ind will apply and will expire SIX (6) atute, cause the application to become	nay a reply be timely filed of thirty (30) days will be considered MONTHS from the mailing date of the ABANDONED (35 U.S.C. § 133)	his communication
Status 1	,		
1)⊠ Responsive to communication(s) filed on 30	0 July 2003.	•	
	his action is non-final.		
3) Since this application is in condition for allo		matters, prosecution as to	the merits is
closed in accordance with the practice under			
Disposition of Claims	;		
4)⊠ Claim(s) <u>1-45</u> is/are pending in the applicati	on		
4a) Of the above claim(s) is/are without 5) is/are allowed. 5) Claim(s) is/are allowed. 6) Claim(s) <u>1-45</u> is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and	Irawn from consideration		
Application Papers	. 4		
9) The specification is objected to by the Exam	iner.		
10) The drawing(s) filed on is/are: a) □ a	ccepted or b) objected	I to by the Examiner.	
Applicant may not request that any objection to t	he drawing(s) be held in ab	eyance. See 37 CFR 1.85(a)
Replacement drawing sheet(s) including the corr			
11) The oath or declaration is objected to by the	Examiner. Note the attac	ched Office Action or form	PTO-152.
Priority under 35 U.S.C. § 119			
12) Acknowledgment is made of a claim for forei a) All b) Some * c) None of:	gn priority under 35 U.S.	C. § 119(a)-(d) or (f).	
1.☐ Certified copies of the priority docume	ents have been received.		
2. Certified copies of the priority documents have been received in Application No.			
3. Copies of the certified copies of the p	riority documents have be	een received in this Nation	nal Stage
application from the International Bure	` ',,		
* See the attached detailed Office action for a li	st of the certified copies	not received.	
Attachment(s)		1	
1) Notice of References Cited (PTO-892)	4) 🔲 Intervi	ew Summary (PTO-413)	
Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/0 Paper No(s)/Mail Date	Paper	No(s)/Mail Date of Informal Patent Application (F	°TO-152)
U.S. Patent and Trademark Office PTOL-326 (Rev. 1-04)	Action Summary	Part of Paper No./N	Mail Date 040804

Art Unit: 3712

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 5, 8, 12, 14-17, 20, 23, 27, 29-32, 35, 38, 42, 44 and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Goen Seminars Stop Smoking Workbook ("Goen"). Goen discloses a method and system for helping a subject to stop smoking comprising a non-conditional educational program, a hypnosis program and a substance selected fro the recited group. In particular, pages 3-5 of the workbook comprise a non-conditional educational program which educates the conscious mind to discourage smoking, page 3 discloses the use of a hypnosis program to help the user stop smoking, and page 6 discloses the use of a vitamin supplement as part of the system. With respect to claims 2, 8, 12, 14, 15, 17, 23, 27, 29, 30, 32, 38, 42, 44 and 45, Goen discloses on page 6 the use of lobelia, which is a "stop-smoking substance" as well as a nicotine receptor antagonist, in an amount effective to aid in reducing a craving to smoke tobacco. With respect to claims 5, 20 and 35, Goen discloses on page 6 the use of vitamin supplements including vitamin C, calcium and magnesium.

Art Unit: 3712

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3, 4, 18, 19, 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goen in view of Ferry, "Nicotine Dependence: America's 'Drug of Choice' " ("Ferry"). Goen discloses all of the limitations of the claims with the exception of the use of a weight control substance and the use of buproprion hydrochloride. Ferry discloses at page 11 (Section IX, H) the use of phenteramine to control weight. It would have been obvious to one of ordinary skill in the relevant art to modify the method and system disclosed by Goen by providing a weight control substance for the purpose of reducing nicotine craving. Ferry also discloses at page 10 (Section XIII, B) the use of buproprion hydrochloride as a stop smoking substance. It would have been obvious to one of ordinary skill in the relevant art to modify the method and system disclosed by Goen by providing buproprion hydrochloride for the purpose of assisting the user to stop smoking.

Claims 6, 7, 9, 11, 21, 22, 24, 26, 36, 37, 39 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goen in view of Umbdenstock. Goen discloses all of the limitations of claims 6, 7, 21, 22, 36 and 37 with the exception of the use of dietary supplements including gotu kola and kava kava. Umbdenstock discloses in column 9, line 3 to column 10, line 20 the use of dietary supplements including gotu kola and kava

Art Unit: 3712

kava as part of a program to curb an addiction. It would have been obvious to one of ordinary skill in the relevant art to modify the system and method disclosed by Goen by providing dietary supplements including gotu kola and kava kava for the purpose of supplying needed nutrients to the user. With respect to claims 9, 11, 24, 26, 39 and 41, kava kava is an anxiolytic.

Claims 9, 10, 24, 25, 39 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goen in view of Gawin. Goen discloses all of the limitations of claims 9, 10, 24, 25, 39 and 40 with the exception of the use of an anxiolytic drug. Gawin discloses in column 5, line 14 to column 6, line 37 the use of anxiolytic drugs as part of a program to curb an addiction. Gawin further discloses in column 3, lines 21-67 that the drugs can be used to help curb a nicotine addiction. It would have been obvious to one of ordinary skill in the relevant art to modify the system and method disclosed by Goen by providing an anxiolytic drug for the purpose of assisting the user in curbing a nicotine addiction.

Claims 9-12, 25-28 and 39-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goen in view of Cary. Goen discloses all of the limitations of claims 9, 10, 24, 25, 39 and 40 with the exception of the use of an anxiolytic drug. Cary discloses in column 2, lines 48-56 the use of anxiolytic drugs as part of a program to curb a nicotine addiction. It would have been obvious to one of ordinary skill in the relevant art to modify the system and method disclosed by Goen by providing an anxiolytic drug for the purpose of assisting the user in curbing a nicotine addiction.

Art Unit: 3712

Coen discloses all of the limitations of claims 12, 13, 27, 28, 42 and 43 with the exception of the use of a nicotine receptor antagonist drug. Cary discloses in column 2, line 57 to column 3, line 62 the use of nicotine receptor antagonist drugs as part of a program to curb an addiction. It would have been obvious to one of ordinary skill in the relevant art to modify the system and method disclosed by Goen by providing a nicotine receptor antagonist drug for the purpose of blocking physiologic, behavioral and reinforcing effects of nicotine. With respect to claims 14, 15, 29, 30, 44 and 45, Goen discloses the use of lobelia, as discussed above. Lobelia is a nicotine receptor antagonist.

Response to Arguments

Applicant's arguments with respect to claims 1-45 have been considered but are moot in view of the new ground(s) of rejection.

With respect to applicant's argument that Ferry does not qualify as prior art, because it cannot be established that the reference was published more than 1 year prior to applicant's priority date of October 25, 1999, applicant is incorrect on this point as a matter of law. 35 USC 102(b) requires that a prior art document be published more than one year before the effective filing date. However, 35 USC 102(a) reads as follows:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Art Unit: 3712

The only requirement is that the reference be published before the effective filing date of the application. Perry bears a copyright date of 1998, which is earlier than the effective filing date of October 25, 1999, and thus qualifies as prior art under 35 USC 102(a). Because 35 USC 103 incorporates all of 35 USC 102, and not only 35 USC 102(b), Ferry qualifies as prior art.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and In re-Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). Applicant is incorrect, as a matter of law, that 35 USC 103 requires that some reference must say, in particular, to combine two specific references together. In this case, all of the secondary references are explicitly directed to methods and systems for curbing a nicotine addiction, and all of the substances disclosed therein are specifically taught, in the secondary references, as being helpful in curbing nicotine addiction. As one example, Cary recites at column 3, lines 8-11, that "[in] the context of nicotine dependence, mecamylamine HCl has been shown to block many of the physiologic, behavioral, and reinforcing effects of nicotine." This is not some made-up reason for combining the references; this is a specific hint, directly quoted from Cary, as to why someone of ordinary skill would include a nicotine receptor antagonist in a system to help a user

Art Unit: 3712

stop smoking. Thus, the present invention is disclosed or suggested when viewing the prior art as a whole.

Because new grounds of rejection are presented herein, this action is made non-final.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kurt Fernstrom whose telephone number is (703) 305-0303. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Derris Banks can be reached on (703) 308-1745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KF April 8, 2004 Ket Feb.